

Appl. No. 10/805,099 (Docket 099/004)
Amdt. dated Dec. 13, 2006
Reply to Office Action of July 13, 2006

REMARKS/ARGUMENTS:

Applicants canceled claims 11-16 without prejudice or disclaimer. Applicants reserve the right to reintroduce the subject matter of those claims at a later point in prosecution. Applicants amended claims 1, 3, 4, 6, and 8-10. Claims 1-10 are now pending in this application. Reconsideration and allowance of the application is respectfully requested.

Priority

The Office noted that Applicants have "complied with conditions for receiving the benefit of an earlier filing date of 7/12/2001" for claims 1-10. Action at page 2. However, the Office argued that claims 11-16 are "only adequately disclosed in the instant application" and therefore Applicants are not entitled to the earlier filing dates for those claims. *Id.* Applicants disagree with the Office's characterization of the disclosure of the earlier priority applications, but have canceled claims 11-16 without acquiescence in the Office's arguments to facilitate prosecution and allowance of claims 1-10.

Information Disclosure

The Office stated that it could not locate copies of the non-patent literature listed in Applicants Information Disclosure Statement ("IDS") filed January 17, 2006. Action at page 3. Although Applicants believe that they submitted such copies with the IDS, Applicants will resend the copies for the convenience of the Office. The resend of the copies of the listed non-patent references will include references AR and BA.

Specification

The Office objected to the specification "because it contains an embedded hyperlink" Action at page 3. Applicants have amended the specification with this paper such that it no longer contains the hyperlink.

Appl. No. 10/805,099 (Docket 099/004)
Amdt. dated Dec. 13, 2006
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Claim Objections

The Office objected to claim 1 for "reciting in b) 'differentiate into areas.'" Action at page 4. Without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have removed the limitation containing that phrase from the claims, so that objection is now moot.

The Office objected to claims 9 and 10 for reciting the phrase "medium containing", arguing that the phrase should be restated as "medium comprising." Action at page 4. The Office's objection relied on its interpretation of the term "containing" as being closed claim language, and the Office suggests that "open claim language 'comprising' would be more appropriate in the instant claims." *Id.*

Applicants traverse this objection. Both the MPEP and Federal Circuit case law make clear that the term "containing" is an open term and "is synonymous with 'comprising' and 'including'." *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369 (Fed. Cir. 2004); *see also* MPEP §2111.03. Therefore, Applicants respectfully request that the Office withdraw these objections.

Rejection under 35 U.S.C. §112, first paragraph (enablement)

The Office rejected claims 1-16 under 35 U.S.C. §112, first paragraph, as allegedly not being enabled by the specification. Action at page 4. The Office stated that the specification is "enabling for a method of generating cardiomyocytes or cardiomyocyte precursors cells from human embryonic stem (hES) cells obtained from a human blastocyst comprising initiating differentiation of the hES by forming embryoid bodies (EB) in suspension culture" *Id.* However, the Office argued that the specification "does not reasonably provide enablement for a method comprising initiating differentiation of any pPS cell collecting any differentiated cells and generating a cell composition containing cardiomyocyte and cardiomyocyte precursors only." *Id.* at pages 4-5.

Applicants respectfully disagree and traverse the enablement rejections. However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended the claims such that the claims are now directed to human embryonic stem

Appl. No. 10/805,099 (Docket 099/004)
Amdt. dated Dec. 13, 2006
Reply to Office Action of July 13, 2006

cells instead of primate pluripotent stem cells. This should obviate the Office's concerns "that the specification and the art does not provide guidance disclosing methods of generating EB from any other cells type other than ES cells" Action at page 6. With regard to the Office's other concern regarding the homogeneous populations, Applicants note that the term "containing" is not closed claim language (as discussed above), and therefore the claims do not require a homogenous population of cardiomyocyte or cardiomyocyte precursor cells as stated by the Office.

For at least the above reasons, Application request reconsideration and withdrawal of the enablement rejections.

Rejection under 35 U.S.C. §112, second paragraph

The Office rejected claims 1-16 under 35 U.S.C. §112, second paragraph for various reasons. The Office argued that it is unclear what breadth the Applicants are claiming because claims 1 and 16 recite primate pluripotent stem cells obtained from a human blastocyst. Action at page 8. Applicants disagree that this scope is unclear. However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended claim 1 such that it now recites human embryonic stem cells. Claim 16 is now canceled. Thus, this basis for the rejections is now moot.

The Office also argued that the phrase "such as" in claims 3 and 4 render those claims indefinite. Action at page 8. Without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended claims 3 and 4 such that they no longer recite the phrase "such as". Thus, this basis for the rejections is now moot.

The Office contended that the term "about" in claims 6 and 13 render those claims indefinite. Applicants disagree with the Office's characterization of the term about as indefinite. However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended claim 6 such that it no longer recites the term "about". Claim 13 is now canceled. Thus, this basis for the rejections is now moot.

Appl. No. 10/805,099 (Docket 099/004)

Amdt. dated Dec. 13, 2006

Reply to Office Action of July 13, 2006

The Office argued that the phrase "according to" "in claims 1 and 8 only implies a level of agreement with something" and as such the "metes and bounds of 'according' are unclear." Action at page 9. Applicants disagree with the Office's interpretation of "according to." However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended claims 1 and 8 such that they no longer recite the phrase "according to". Thus, the basis for these rejections is now moot.

The Office contended that the limitation "the collected cells" lacks sufficient antecedent basis. Action at page 9. The Office argued that the "cells are collected in several steps of the method." Id. However, Applicants note that there was only one collection step in the claims before they were amended. Regardless, claims 9 and 10 have now been amended as noted above. Thus, the basis for these rejections is now moot.

The Office stated that trademarks "can not be claimed." Action at page 9. The Office cited no authority for such a statement, which is inaccurate. The MPEP states that "if the product to which the trademark refers is set forth in such language that its identity is clear, the examiners are authorized to permit the use of the trademark if it is distinguished from common descriptive nouns by capitalization. If the trademark has a fixed and definite meaning, it constitutes sufficient identification unless some physical or chemical characteristic of the article or material is involved in the invention." MPEP §608.01(v). The Office has not made any argument or advanced any evidence that the term Mairigel does not have a fixed and definite meaning in the art. Until this is done, the Office has not established a prima facie case of indefiniteness.

For the above reasons, Applicants respectfully request that the Office reconsider and withdraw the outstanding §112, second paragraph rejections.

Rejection under 35 U.S.C. §102(b)

The Office rejected claims 1 and 11-16 under 35 U.S.C. §102(b) as allegedly being anticipated by Xu et al. Applicants traverse the rejection and disagree with the arguments of the Office.

Appl. No. 10/805,099 (Docket 099/004)

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Reply to Office Action of July 13, 2006

However, Applicants make two observations. First, claims 11-16 have been canceled, rendering the rejections of those claims moot. Second, the Office has found that claims 1-10 receive the benefit of the July 12, 2001 filing date. As the Xu reference was not published until 2002, it is not available as a prior art reference against claim 1. Therefore, Applicants request that the Office withdraw the § 102(b) rejection of claim 1.

Rejection under 35 U.S.C. § 103(a)

The Office rejected claims 1-4 and 6-10 under 35 U.S.C. § 103(a) as allegedly being unpatentable over a series of references. Action at page 13.

Applicants traverse the rejections. For an obviousness rejection under § 103(a), "the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143. To do this, the Office relies on the Kehat reference to "teach the culture of pPS cells to generate cardiomyocytes." Action at page 17. However, the Kehat reference is dated August, 2001, which is subsequent to the accorded filing date of July 12, 2001 for claims 1-10. Therefore, the Kehat reference is not available to support this obviousness rejection, and the Office fails to make a prima facie case because, *inter alia*, it has not established all the claim limitations in appropriate references.

Furthermore, the Office relies on an improper standard by citing that the teachings in Kehat show that "it would be inherent that the method described by Doevendans et al. would have produced human cardiomyocytes from pPS cells at the time of filing." Action at page 17. However, there is no "inherent obviousness." What the Office must show instead is that one skilled in the art would have had a reasonable expectation of success in applying the methods of Doevendans to hES cells. The Office has not even attempted such a showing, instead merely making a completely conclusory statement that there would have been a "reasonable expectation of success because all of these methods have been well established in the art." Until the Office puts forth a proper prima facie case of obviousness and explains itself using reasoning and evidence, it fails to adequately support an obviousness rejection of these claims.

Appl. No. 10/805,099 (Docket 099/004)
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Applicants respectfully request reconsideration and withdrawal of the obviousness rejections.

Double Patenting

Applicants note that the double patenting rejections are currently provisional rejections. If any of the cited applications become allowable prior to allowance of the current claims, Applicants will address the rejections on their merits or will file an appropriate terminal disclaimer.

Fees Due

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, Applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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